#### **DETAILED ACTION**

# Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. Claims 1, 3, 4, 15, and 20 are again rejected under 35 U.S.C. 102(b) as being anticipated by Kataoka et al. US Patent No. 5,374,266.

Kataoka et al. disclose a medical laser apparatus for treatment of hard tissue present in fluid filled cavity, such as the dental tissue, the apparatus comprising:

an Er:YAG laser for generating treatment pulses having a wavelength of about 2.94 um; and

an optical fiber system for delivering the treatment laser pulses to the desired dental tissue (see Fig. 7; col. 2, lines 10-33; col. 4, lines 1-13; col. 5, lines 11-18; and Example 3).

Kataoka et al. further teach that the laser system is used for removing dental caries, forming cavities in teeth, treating pulp canals and removing tartar (see col. 2, lines 25-33 and col. 4, lines 1-5). Hence, Kataoka et al. teach the step of applying treatment laser pulses to the hard dental tissue as claimed.

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2. Claims 1 and 10-15 are again rejected under 35 U.S.C. 102(b) as being anticipated by Sinofsky US Patent No. 5,363,387.

Sinofsky discloses a variable pulse-width laser apparatus and method of use for delivering treatment energy to biological tissue, such as the hard dental tissue, for surgical or therapeutic purposes (see Fig. 3 and col. 4, lines 21-27), the apparatus comprising:

an endoscope catheter **90** having an endoscopic port **92** for viewing the treatment site (see Fig. 4);

an Er:YAG laser system adapted to generate the treatment laser pulses (see col. 2, lines 29-34); and

an optical fiber bundle **40** for delivering the treatment laser pulses to the desired tissue, through the irradiation port **17**.

The optical fiber bundle **40** is configured to transmit laser pulses from the laser source, through the handpiece, to treatment site. In the medical art, a handpiece is known as a unit configured to fit the hand of a surgeon/operator. Hence, the optical fiber bundle, which passes through the length of the handpiece is at least longer than 10 cm.

3. Claims 1, 3, 4, 15 and 20 are again rejected under 35 U.S.C. 102(b) as being anticipated by Mueller et al. US Patent No. 5,458,594.

Mueller et al. disclose a laser apparatus and methods of use for the treatment of hard biological material, such as hard dental tissue, the method comprising:

generating laser radiation form an Er:YAG laser source; and

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applying the laser radiation to the hard dental tissue as claimed (see the abstract, and claims 1 and 4).

## Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. Claims 3-9 and 16-22 are rejected under 35 U.S.C. 103(a) as obvious over Sinofsky US Patent No. 5,363,387 in view of Liebernamm et al., US Patent No. 5,971,755.

With respect to claims 3 and 16-18, although Sinofsky, described above, teaches apparatus and method for treating dental tissue with laser energy, he does not specifically teach that the treated oral tissue includes fibrous scar, calculi, salivary stones sublingual glad, parotid duct, or disorders in the temporomandibular joints as claimed. The recited tissue structures are in the mouth of the patient. Moreover, the applicant merely cites the step of delivering the optical energy to said tissue and fails to clearly teach specific steps for providing the treatment. Hence, since Sinofsky teaches apparatus and method of delivering treatment optical energy to the patient's mouth as claimed, the examiner takes the position that he functionally exposes the treatment energy to all tissues in the patient's mouth such as sublingual glad, parotid duct, temporomandibular joints or the like as claimed as claimed.

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With respect to claim 6, Sinofsky does not teach the use of Nahlieli type sialoendoscope as claimed. And, with respect to claims 7-9, 19, 21 and 22, they do not
particularly specify the intensity of the treatment energy. Liebermann et al. teach a
dental treatment laser system and method of use in which an Er:YAG laser provides
treatment laser pulses having energy of between 100 to 500 mJ. Hence, at the time of
the applicant's invention, it would have been obvious to one of ordinary skill in the art to
modify Sinofsky in view of Liebermann et al. and use energy density within the claimed
range for the treatment of the dental tissue. It would have been further obvious to one of
ordinary skill in the art to use any commercially available endoscope that is suitable for
insertion of small body cavities, such as oral cavities because no advantage of the
recited particular type is claimed.

### Response to Arguments

5. Applicant's arguments, see page 9, line 16-26, filed May 26, 2009, with respect to claims 1 and 3-22 have been fully considered and are persuasive. The rejection of claims 1 and 3-22 under 35 U.S.C 103(a) directed to Temelkuran et al., US Patent No. 5,971,755, has been withdrawn.

With respect to Kataoka ('266), Sinofsky ('387), and Mueller ('594), applicant's arguments filed on May 29, 2009 have been fully considered but they are not persuasive. The applicant summarizes the teachings of the prior art record. In particular, the applicant describes the structures of the treatment system of the prior art of record to distinguish the claimed invention over the references. The applicant argues that the

references fail to disclose, teach or suggest a method of delivering laser energy into a fluid filled oral cavity with diameter of 3 mm or less, such as the salivary duct or temporomandibular joint as claimed. The applicant further notes a surprising finding in using Er:YAG laser for successful treatment of small body cavities as claimed.

In response to the applicant's remarks directed to the structures of the treatment system in the above prior art references, the applicant's claims fail to teach structural limitations other than the use of Er:YAG laser, delivery optical fiber, and an endoscope. As described in the body of this Office Action, the prior art of record teaches the claimed structures of the treatment apparatus.

With respect to the argument that the prior art of record fails to teach a method of delivering treatment energy to small oral cavities, such as the salivary duct or temporomandibular joint, the prior art of record teaches the step of delivering treatment energy to a patient's mouth. The examiner's position is that the step of delivering treatment energy to the mouth exposes said energy to all oral tissues including small oral cavities such as salivary ducts and temporomandibular joints as claimed. Hence, the prior art of record functionally teaches the recited method steps of the instant application as broadly as claimed.

With respect to the argument directed to the unexpected results/advantage for using Er:YAG laser for the treatment of small oral cavities, the references of Kataoka ('266), Sinofsky ('387), and Mueller ('594) teach methods for treating oral tissue by exposing optical energy produced by an Er:YAG laser to the oral tissue, including small oral cavities. Hence, the prior art of record teaches the step of exposing Er:YAG laser

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energy to small oral cavities such as salivary ducts and temporomandibular joints as claimed.

### Conclusion

6. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Friedman US Pat. No. 6,450,170. teaches apparatus and method for delivering optical energy to oral tissue in a patient's mouth such as temporomandibular joints or the like.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ahmed M. Farah whose telephone number is (571) 272-4765. The examiner can normally be reached on Mon, Tue, Thur and Fri between 9:30 AM 7:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johnson Henry can be reached on (571) 272-4768. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic

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Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Ahmed M Farah/ Primary Examiner, Art Unit 3769

August 31, 2009.